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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,603	06/08/2005	Tatsuhiko Kodama	14875-137US1	5647

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FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/516,603	Applicant(s) KODAMA ET AL.	
	Examiner Marcia S. Noble	Art Unit 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 June 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☒ Newly proposed or amended claim(s) *19 and 21* would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *4-8,19 and 21*.
   Claim(s) withdrawn from consideration: *1-3 and 10-18*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

PETER PARAS, JR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of 3. NOTE: Newly added claim 21 would introduce a new enablement rejection. Claim 21 recites "a transgenic mouse that comprises a gene encoding a baculovirus membrane protein gp64". This limitation encompasses a transgenic mouse that that does not express the transgene. For the instant method to be effective, the trangenic mouse must express the transgene for the method to produce the antibody product as intended by the specification. Therefore, since the instant claim encompasses a transgenic mouse that does not express the transgene, and transgene expression is essential to the method but has not been required by proposed claim 21, claim 21 would not be considered enable. Therefore, since the newly added claim introduces new enablement issues, the amendment to the claims will not be entered .

Continuation of 11. does NOT place the application in condition for allowance because:
New Matter
Claims 4, 6-8 and 19 stand rejected under 112, 1st paragraph for reciting new matter. The recitation "in an expressible manner" was deemed new matter. The amendment to the claims would remove this recitation and therefore the claims would no longer comprise new matter. However, because the proposed claims are not being entered, the instant rejection is maintained.

112, 2nd Paragraph
Claims 4 and 6-8 stand rejected under 112, 2nd paragraph for their indefinite recitation, "the transgenic mouse animal". The proposed amendement to the claims would remove this recitation and specify a transgenic mouse, which would clarify the claim. However, because the proposed claims are not being entered, the instant rejection of record is maintained.

Scope of Enablement
Claims 4 and 6-8 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:
A method for producing an antibody against an antigen, wherein the method comprises the steps of: (a) preparing a baculovirus that comprises a DNA which encodes an antigen or an epitope thereof; (b) infecting a host cell with the baculovirus of (a) to obtain a budding virus that expresses said antigen or an epitope thereof;(c) producing a transgenic mouse that expresses a gene encoding the baculovirus membrane protein gp64, (d) immunizing the transgenic mouse of (c) with a fraction comprising the budding virus of (b); and (e) recovering an antibody-specific for said antigen from the immunized animal, does not reasonably provide enablement for A method for producing an antibody against a target antigen, wherein the method comprises the steps of: (a) preparing an immunogen comprising the target antigen and any background antigen; (b) producing any transgenic non-human animal comprising a gene expressibly encoding any background antigen; (c) administering the immunogen of (a) to the transgenic non-human animal of (b); and (d) isolating the antibody against the target antigen from the transgenic non-human animal.

Applicant traverses this rejection on the grounds that contrary to the unpredictable transgenic animals disclosed in the art of the enablement rejection, the instant transgenic mice need only express as much of the antigen as required to induce immunotolerance and the art of the enablement rejection encompasses far more complex phenotypes than that the expression required to induce immunotolerance.

This argument is not found persuasive because regardless of complexity the phenotypes disclosed in the cited art, it suggests that obtaining any phenotype is highly unpredictable, ie-often times for various reasons no expression is encountered. Providing sufficent expression of the transgene to induce an immune response, as encompassed by the claims, would require adequate expression of the transgene even it the requirement is low levels of expression. This phenotype would still be considered unpredicable by the art. Only when specific guidance is provided to the production of a specific transgenic mouse with a specific phenotype can this unpredictability be overcome. Again the specification does not provide this level of guidance for the breadth encompassed by the transgenic mice expressing any background antigen. Therefore, the specification is not enabling for a transgenic mouse expressing any background antigen.

Continuation of 13. Other: A discussed in item 6, amended claims 19 and 21 would be allowable with some revision. It is suggested that claim 19 step (c) be amended to recite a transgenic mouse that comprises IN ITS GENOME a gene encoding....It is also suggested that claim 19 step (e) be amended to recite ...PepT1 from the TRANSGENIC immunzed mouse, to have proper anticedent basis. Its is also suggested that claim 21 (c) be amended to recite ...a transgenic mouse that comprises IN ITS GENOME a gene encoding a baculovirus membrane protein gp64 WHEREIN THE MOUSE EXPRESSES THE BACULOVIRUS MEMBRANE PROTEIN GP64 AND HAS IMMUNOTOLERANCE TO GP64. It is also suggested that claim 21 step (e) be amended to recite "OR epitope" instead of "of epitope".